

PSJ18 WALGREENS Opp Exh 15



Internal Audit Report

Date December 22, 2008

Subject DEA Compliance – Perrysburg Distribution Center

From L. Dettmer – Internal Audit
B. Kowalski – Internal Audit
J. VanOverbake – Internal Audit
B. Yarbrough – Internal Audit

To Steve Kneller, Manager – Perrysburg Distribution Center
Dan Coughlin, Regional Vice President – Distribution Centers and Logistics

cc K. Amos, D. Boyajian, D. Brandt, R. Delaney, D. Doyle, T. Gorman, G. Hodge,
B. Leander, R. Lewis, M. Linden, S. Malusa, G. Peters, D. Pinon, B. Rogan,
T. Steffen, T. Trumbull, K. Wilson, C. Young

Conclusion

In our opinion, internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain unremediated. Areas requiring the greatest level of improvement are as follows:

DC-wide:

- pseudoephedrine reporting requirements and inventory maintenance
- suspicious controlled drug order processing and reporting
- controlled drug reporting, specifically receiving record information
- lack of formalized CII controlled substance policies and procedures

Perrysburg DC:

- significant concern regarding the growing in-transit controlled drug losses
- controlled drug security procedures
- employee background screening documentation
- controlled drug receiving procedures

Areas noted for improvement were reported to Management with suggestions for improved compliance. Management has corrected or is in the process of taking appropriate action to resolve our noted concerns.

Background

Internal Audit's (IA) examination for compliance with DEA regulations and Company policies for the distribution of controlled drugs was conducted November 17 - 21, 2008. Company policies and procedures regarding controlled drugs are communicated to the DCs via the online Compliance Manual.

The Perrysburg DC is licensed to handle Schedule II through V controlled drugs and was last visited by the DEA in May 2006. A subsequent meeting with the DEA was held in January 2008 to address their growing concern regarding in-transit losses the DC has been experiencing.

Objective

The purpose of our review was to ascertain if the Perrysburg DC is in compliance with DEA regulations and Walgreens policies relating to controlled drug distribution, handling, and reporting. In addition, our review verified whether any previously noted deficiencies have been corrected or are in the process of remediation.

Scope

The review focused on the internal controls established by Walgreens DCs to ensure compliance with DEA regulation Section 1300 found in Title 21 of the Federal Code of Regulations. To substantiate compliance with Section 1300, we conducted interviews with DC management, documented the movement of controlled drugs from the receiving dock to the shipping dock, and used an audit testing program that encompasses Section 1300 requirements.

Findings

Our review found compliance within the following areas:

- The Pseudoephedrine receiving and shipping reports were generated in a timely fashion.
- The retention of primary controlled substance records is being maintained properly.
- The controlled substance shipping policies and procedures were properly being followed.

Our review disclosed opportunities for improvement of compliance controls in the areas specified below. Management has addressed our concerns and corrective action has either been performed or is in the process of remediation. Detailed descriptions of our findings and recommendations, along with management responses, are included in Attachment A as indicated.

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We would like to thank the Perrysburg Team for their cooperation and hospitality during our review.

Perrysburg DC DEA Review – 12/22/08

Attachment A

Summary of Findings

Issue	Risk	Recommendation	Management's Response
Pseudoephedrine (PSE) Reporting Requirements			
<p>1. Approximately ten states classify PSE products as a C-V controlled drug under the specific states' Controlled Drugs Act, and one state, Oregon, classifies these products as a C-III controlled drug. During on-site inspections, the DEA typically performs an inventory audit on a sample of controlled drugs, which could include PSE products.</p> <p>I. Specific to our review at the Perrysburg Distribution Center (DC):</p> <p>1. Internal Audit (IA) noted that the PSE item selected for an inventory audit was short seven SKUs compared to the SIMS on-hand count.</p> <p>2. IA was unable to perform an inventory audit on a PSE item due to the inability to obtain a Beginning Balance from the AS/400 Audit Trail. The AS/400 Audit Trail does not keep the daily balances for non-controlled drugs.</p>	<p>The inability to perform an inventory audit may lead to unknown inventory variances, which could be an indication of shrink or concealed shortages. In addition, ineffective record keeping and monitoring of PSE items could lead to potential non-compliance with DEA regulations regarding PSE security.</p> <p>Furthermore, DCs, company-wide, may not know what reporting is required for PSE items. Consequently, the DCs may be unable to produce the necessary information at the time of DEA inspections.</p>	<p>1. The DC should relocate all PSE items into the Rx Area for increased security and camera coverage.</p> <p>2. The Corporate Information Systems Engineer (ISE) Department should provide all DCs with the same PSE data retrieval and reporting as controlled drugs (i.e. historical on-hand counts and DEA required information).</p> <p>3. In the future, when DCs perform their weekly inventories on five randomly selected PSE items, any discrepancies found should be investigated and reported in accordance with the guidelines set forth in Code of Federal Regulations: 1314.15. See Attachment B for Code of Federal Regulations: 1314.15 details and loss reporting format.</p>	<p>Steve Kneller, Distribution Center Manager</p> <p>1. Agreed. The DC has moved all PSE Items into the Rx area.</p> <p>Estimated Completion Date: Complete.</p> <p>Dan Coughlin, Regional Vice President Distribution Centers and Logistics</p> <p>2. We agree with the recommendation; however, before any system modifications are made, we are requesting a legal opinion regarding the applicable PSE laws and regulations which state the PSE records need to be presented and retrieved similar to current controlled substance reporting. A request for the mentioned legal opinion was submitted to Corporate and Regulatory Law on December 1, 2008.</p> <p>Legal Opinion Estimated Follow-up Date:</p> <p>May 31, 2009</p>

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Perrysburg DC DEA Review – 12/22/08

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Summary of Findings

Issue	Risk	Recommendation	Management's Response
<p>3. IA obtained the receiving report for the PSE item and noted the report was missing the vendor's DEA number.</p> <p>II. Based on the current and past DEA reviews and discussions with DC Management, IA has noted direction is unclear with respect to identification and reporting of concealed shortages, overages or other losses of PSE products.</p>			<p>3. Agreed. The compliance manual has been updated to reflect the reporting requirements with the proper form.</p> <p>Estimated Completion Date: Complete.</p>

Controlled Drug Reporting

<p>2. Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled drugs that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery.</p> <p>Walgreens produces a monthly <i>Suspicious Controlled Drug Orders</i> report. Redacted – Attorney Client Privileged</p>	<p>Redacted – Attorney Client Privileged</p>	<p>We recommend discussions continue with the cross-functional team consisting of the Logistics, Corporate and Regulatory Law, and Loss Prevention Departments to assess.</p> <p>Redacted – Attorney Client Privileged</p>	<p>Dan Coughlin, Regional Vice President Distribution Centers and Logistics</p> <p>We will coordinate another meeting during the third quarter to continue discussions on reporting suspicious controlled drug orders.</p> <p>Estimated Date for Next Cross-Functional Meeting for the Updated Suspicious Controlled Drug Order Identification Methodology:</p> <p>May 31, 2009</p>
	Redacted – Attorney Client Privileged		

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Perrysburg DC DEA Review – 12/22/08

Attachment A

Summary of Findings

	Issue	Risk	Recommendation	Management's Response
	<p>Redacted – Attorney Client Privileged</p> <p>Audit Note: During Fiscal 2008, a cross-functional team consisting of representatives from Legal, Distribution, Loss Prevention, and Internal Audit was formed.</p> <p><small>Redacted – Attorney Client Privileged</small></p>			<p>Estimated Completion Date for the New Reporting:</p> <p>June 30, 2009</p>
	<p>Redacted – Attorney Client Privileged</p>			
3.	<p>In order to provide a complete record of the origin of controlled drugs, the DEA requires specific information, such as vendor name and address, to be recorded on the receiving records.</p> <p>The results of our controlled drug inventory audit and historical data testing for the Receiving Report</p>	<p>The DC may not be able to substantiate the vendor or where receipts originated from. Consequently, the DCs may be unable to produce the necessary information at the time of DEA inspections.</p>	<p>IA agrees with DC Management that the residual risk is minimal and no further action is required.</p>	<p>Dan Coughlin, Regional Vice President Distribution Centers and Logistics</p> <p>The Regional Vice President of Distribution Centers and Logistics responsible for DEA compliance has detailed that information prior to December 2008 will have to rely on paper</p>

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Perrysburg DC DEA Review – 12/22/08

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Summary of Findings

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<p>(REPB 309) disclosed three of seven (43%) reports were missing the vendor shipping addresses.</p> <p>As of December 2008, the Receiving Report has been systematically re-developed to ensure all DEA required information is populated on the report moving forward.</p> <p>In light of the programming change, IA feels there is a moderate probability the Receiving Report will not display the Vendor Address or DEA number due to limitations within the AS/400 programming logic for historical receiving data storage before December 2008.</p>			<p>copies, as the electronic data is unavailable. This represents a risk in that our company will have to supplement electronic formats with paper reports. In the mean time, Corporate Information Systems Engineering is researching the quantity of instances in AS/400 where the vendor address or DEA number is not stored.</p> <p>Estimated Completion Date: Not Applicable</p>

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Perrysburg DC DEA Review – 12/22/08

Attachment A

Summary of Findings

	Issue	Risk	Recommendation	Management's Response
4.	<p>The DEA requires the registered purchaser to return all unused DEA Form 222s to the nearest Office of Administration if the purchaser discontinues business.</p> <p>Our review of fifteen closed stores serviced by the DC disclosed the DC had fifteen (100%) closed stores with DEA Form 222s on-hand.</p>	<p>The use of an inactive DEA Form 222 could lead to inadequate shipping documentation, creating potential non-compliance.</p>	<p>Redacted – Attorney Client Privileged</p> <p>2. The DC should develop a quarterly review process to compare stores with unused DEA 222 Forms against closed stores the DC serviced.</p>	<p>Steve Kneller, Distribution Center Manager</p> <p>The DC will run a query the first of each month that identifies all closed stores that have DEA Form 222s on file. Once the closed stores are identified, the forms will be sent back to the regional DEA Office (Columbus, Ohio) to be destroyed.</p> <p>Estimated Completion Date: Complete.</p>
5.	<p>The DEA requires specific information to be properly documented for CII controlled drug receipts and shipments on the DEA Form 222s.</p> <p>Our review of ten DEA Form 222s for DC receipts disclosed one (10%) form was not completely filled out. The line item was not properly documented due to the product not being received.</p>	<p>The DC may not be including all required information on DEA Form 222s, which could lead to inadequate receiving and shipping documentation.</p>	<p>If receipts do not arrive on the scheduled date, the DEA Form 222 should be noted accordingly that zero packages were received with a slash to document if the control drugs are received at later date.</p>	<p>Steve Kneller, Distribution Center Manager</p> <p>DC will place a (0) zero in each item that is listed on a DEA Form 222 but no quantity is received for. This process began on 11/18/08 and all CII receiver checkers have been trained.</p> <p>Estimated Completion Date: Complete.</p>

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Summary of Findings

Issue	Risk	Recommendation	Management's Response
6. DCs are required to print the monthly Automation of Reports and Consolidated Orders System (ARCOS) transaction reports that have been submitted to the DEA to ensure completeness and accuracy of transactions. Discussions with the CII Function Manager disclosed the monthly transaction review is not being performed.	There is a lack of assurance all transactions have been completely and accurately transmitted to the DEA if the monthly transaction review is not performed.	Each month, ARCOS transactions reported to the DEA should be verified to the DC's internal ARCOS spreadsheet, per Company policy.	Dan Coughlin, Regional Vice President Distribution Centers and Logistics The Logistics and IA Departments will meet in May 2009 to discuss the continuation and viability of the report. The monthly report is approximately 1,800 pages and requires each line item to be verified against the DCs' AS/400. At the present time, printing the report is cost prohibitive. Estimated Completion Date for Report Continuation Decision: May 31, 2009
7. During January 2008, a meeting was held between the DEA and Perrysburg DC to address the DEA's growing concern regarding reported in-transit losses. To limit the potential for in-transit losses, the DEA recommended that the CII Manager's name from the shipping label and the "CII" label on the tamper proof bag be removed. Our review disclosed the	CII controlled drugs could be easily identified and may be susceptible to diversion.	The DC should remove: 1. The CII Manager's name from the shipping labels 2. The "CII" label on the tamper proof bags.	Bob Rogan, Regional Vice President Distribution Centers 1. Agreed. The CII managers name appearing on the label has been changed and replaced by a period (.). 2. Having the "CII" no longer printed on the bag will be effective with the next bag order from the vendor. This will not

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Summary of Findings

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above is still present. In addition, our review of DEA Form 106s subsequently filed since January 2008 disclosed twenty-nine instances of reported in-transit losses valued at approximately \$82,500, indicating a loss in-transit issue still exists at the Perrysburg DC.			be until approximately May 31, 2009, since there are a large number of bags in stock that still have the printing. Estimated Completion Date: 1. Complete. 2. May 31, 2009

Controlled Drug Security

8.	Walgreens policy requires controlled drug receipts to be in the custody of an employee until they are checked into the controlled drug cages. During the controlled drug cage alarm testing, IA noticed an unattended pallet of CIII-V controlled drugs not locked up in the transport cages, waiting to be lifted into the CIII-V cages.	Unattended controlled drugs are susceptible to diversion and contrary to company policy.	We recommend management reiterate the policies and procedures regarding the transportation of controlled drugs from the receiving dock to the controlled drug cages to all applicable employees.	Steve Kneller, Distribution Center Manager The Controlled Drug Transport Process has been reviewed with all Transport Drivers and Rx, Receiving, and FCS Function Managers. Estimated Completion Date: Complete.
9.	During the controlled drug vault and cage alarm test, IA evaluates the camera coverage for adequacy, ensuring there are no areas within the cages without camera coverage (blind spots). Our evaluation of camera coverage	Inadequate security camera coverage limits the ability to monitor activity within the controlled drug cages and the ability to observe or record the occurrence of theft.	The Asset Protection (AP) Office should install a camera to provide coverage at the back end of the pick to light area in the CII vault. We also recommend that cameras be repositioned to cover blind spots in the CII vault at the end of the pick to light area and in the CIII-V cages	Steve Kneller, Distribution Center Manager Disagreed. The current camera placement has been approved by the DEA. Estimated Completion Date:

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Perrysburg DC DEA Review – 12/22/08

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Summary of Findings

	Issue	Risk	Recommendation	Management's Response
	in controlled drug cage and vault disclosed three significant blind spots.		at the audit stations.	Not Applicable.
10.	<p>During the controlled drug cage alarm testing, IA attempts to trigger all motion detectors. The results from the DC's security system and the central monitoring station's report are reviewed to ensure all motion detectors were transmitted to the AP Office and central monitoring station.</p> <p>The results of the alarm test disclosed:</p> <ol style="list-style-type: none"> 1. Two motion detectors did not activate per AP's Pinnacle Alarm testing report. 2. Ten motion detectors activated per AP's Pinnacle Alarm testing did not trigger on the central monitoring station's report. 	<p>Inactive motion detectors limit the effectiveness of the controlled drug cages security system.</p> <p>In addition, the central monitoring station can not effectively monitor the DC's alarm system if motion detectors triggered at the DC do not register at the station.</p>	<p>We recommend the DC work with the central monitoring station to ensure all DC motion detectors are operating effectively and synchronized with the central monitoring station.</p>	<p>Steve Kneller, Distribution Center Manager</p> <p>The AP Function Manager has worked with FE Moran, our central monitoring station, and resolved these issues.</p> <p>Estimated Completion Date: Complete.</p>

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Summary of Findings

Issue	Risk	Recommendation	Management's Response
11. The AP Office is required to have controlled drug cage layouts that accurately illustrate the motion detector and camera locations. In addition, the layout is used during the quarterly alarm test to ensure all motion detectors have been accounted for and triggered. During our review it was noted the controlled drug cages and vault layout diagrams did not adequately represent the current layout. In addition, the diagrams also lacked the motion detector assignment numbers from AP's Data Sheets and did not account for camera coverage.	There is no assurance AP can monitor and test all alarm points in the cages and vault.	We recommend AP Management review the current adequacy of the controlled drug cages and vault layout diagrams and make necessary updates to include the alarm point assignment numbers and cameras.	Steve Kneller, Distribution Center Manager The AP DC/Transportation Manager and AP Function Manager have worked with the DC Industrial Engineer to ensure that the alarm point numbers and cameras are correct to the drawing. Estimated Completion Date: Complete.
<u>Controlled Drug Cage Access</u>			
12. Permanent and temporary access to the controlled drug cages should be approved by a Function Manager or above and recorded in the Card Access Log, per the AP Instruction Manual. During our review it was noted the DC does not keep records for the request for changes to permanent access to the controlled drug cages.	Unnecessary access may be granted to the controlled drug cages without the proper approval of DC Management.	We recommend that no changes should be made to Threshold permanent access unless Function Manager or above approval e-mail is obtained. This should be filed in an electronic folder for a period of time determined by management. In addition, the Card Access Log for temporary access should be used in accordance with the AP	Steve Kneller, Distribution Center Manager The AP Function Manager has created a log for both permanent and temporary access for the controlled cage. AP will call Inbound/Outbound Manager (IO), Operations Manager, Human Resource Manager, or DC Manager to get approval to

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Perrysburg DC DEA Review – 12/22/08

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Summary of Findings

Issue	Risk	Recommendation	Management's Response
In addition, the AP Office does not utilize the Card Access Log for temporary access to the controlled drug cages.		Instruction Manual.	grant access to the controlled cage, including CII access as well. If IO or above is not in the building, the Function Manager (FM) who is in the building may grant temporary access. The AP Office is retaining an e-mail on all permanent changes to access.
13. AP requires all individuals who do not have permanent badge access to use a log to sign in/out of the controlled drug cages. Our review noted that the DC does not utilize the CIII-V controlled cage sign in/out log, tracking individuals who do not have permanent badge access into the cage.	AP may not be able to effectively monitor who is accessing the cage and for what time period, which could lead to unauthorized access.	The DC should utilize a sign in/out sheet for individuals entering the controlled drug cage without card access. AP should review the sign in/out sheet on a weekly basis to monitor access to the controlled drug cage.	Steve Kneller, Distribution Center Manager A clipboard has been added to the CIII-V cage door. Also, we have posted a sign that instructs anyone entering the cage to sign in/out on the log. Rx FMs have been retrained regarding this requirement. Estimated Completion Date: Complete.

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Perrysburg DC DEA Review – 12/22/08

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Summary of Findings

Issue	Risk	Recommendation	Management's Response
14. The AP Office is required to perform a monthly security and safety audit. Results of the monthly audit are reviewed and approved by the DC Manager. Our review of the September and October 2008 Perrysburg AP security and safety audit disclosed: <ol style="list-style-type: none">1. The security and safety audit does not reflect the DC's current security environment with multiple questions relating to the Traccess System, a key locking system that is not utilized by the DC.2. The DC Manager did not provide an approval signature indicating his review and acceptance of the audit results.	If the AP security and safety audit does not reflect the DC's current security environment, potential issues may not be identified timely with corrective action performed. In addition, if the DC Manager does not provide an approval signature, there is less assurance safety and security issues noted in the audit will be adequately addressed.	1. Corporate Loss Prevention/Asset Protection should review the AP monthly Security and Safety audit reports for all DCs to ensure they are current and reflect the actual DCs' security environment. 2. The Perrysburg DC Manager should sign the AP monthly safety and security audit to document his review and approval. Any issues noted in the audit should be addressed and documented in the commentary section.	Tim Gorman, Director, Asset Protection 1. We agree with IA's recommendation. Corporate Loss Prevention/Asset Protection is currently assessing each DCs' current monthly AP safety and security audit to analyze what is required, beneficial, and what may need to be eliminated. The monthly audit will then be updated and distributed to the respective DCs' AP Office. Estimated Completion Date: January 31, 2010 Steve Kneller, Distribution Center Manager 2. Agreed. The AP DC/Transportation Manager and AP Function Manager have created a new monthly recap that has been in place since January 2009. November and December reports have been submitted to the DC Operations Manager for review. Estimated Completion Date: Complete.

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Perrysburg DC DEA Review – 12/22/08

Attachment A

Summary of Findings

	<u>Issue</u>	<u>Risk</u>	<u>Recommendation</u>	<u>Management's Response</u>
15.	Registrants are required to change the CII vault combination periodically or when employee turnover occurs with knowledge of the combination. Discussions with the CII Manager indicated that the DC could not recall the last time the CII vault combination was changed.	Unauthorized access to the controlled drug cages could occur if the vault combination is not changed periodically.	The DC should develop a policy to periodically change the CII vault combination and when there is employee turnover with knowledge of the combination. In addition, the DC should develop a log to monitor/track when the lock combination is changed.	Steve Kneller, Distribution Center Manager The DC has developed a procedure to change the vault combination two times per year (on the day light savings dates). Estimated Completion Date: Complete.
<u>Asset Protection Procedures</u>				
16.	The AP Office is required to utilize the AP Daily Security Walk-through Check List which allows the AP Office to ensure all activities have been performed for the day. Our review disclosed that the AP Office does not utilize the required daily checklist. Note: Discussions with the AP Office indicated one was being developed.	AP personnel may not be fully aware of their responsibilities.	The DC AP Office should continue efforts to develop an AP Daily Security Walk-through Check List. The checklist should be reviewed by the AP Manager and retained for a reasonable period of time.	Steve Kneller, Distribution Center Manager The AP Function Manager has re-created a new daily sheet that is filled out per shift regarding CIII-V walk-throughs to include checking cages on the shipping dock. Estimated Completion Date: Complete.

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Perrysburg DC DEA Review – 12/22/08

Attachment A

Summary of Findings

Issue	Risk	Recommendation	Management's Response
Documentation of Employment Screening Tests and Criminal Background Checks			
17. The DEA requires local background checks and screening tests for all employees having access to controlled substances. In addition, Company policy requires all DC employees complete the DEA Employee Screening Questionnaire and the Criminal Records Inquiry. From a sample of twenty-five employees tested, the following were not completed: Two (8%) DEA Employee Screening Questionnaires One (4%) National Criminal Records Check Eleven (44%) Local Criminal Records Checks for members of management	Failure to perform the required background checks and screening tests may result in the hire of individuals that may be considered unemployable had the checks been performed timely.	<ol style="list-style-type: none"> 1) Take the necessary actions to update the employee personnel files for the missing documentation. 2) Develop a binder containing the four documents for all employees in (1) above that would be immediately available for review by the DEA or other entities. 3) On a quarterly basis, review and update the HR Binder containing DEA required documentation of all employees having regular access to controlled drugs to ensure that all screening tests for all required employees have been executed. 	Steve Kneller, Distribution Center Manager The DC has created a binder of copies for all four employee checks. The missing employee documentation has been obtained and filed in the mentioned binder. Estimated Completion Date: Complete.

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Perryburg DC DEA Review – 12/22/08

Attachment A

Summary of Findings

Issue	Risk	Recommendation	Management's Response
Development of CII Controlled Drug Policies and Procedures			
18. The Logistic and Planning Department utilizes the online compliance manual to communicate management's objectives, policies, and procedures for the CIII-V controlled drug process to ensure compliance with DEA regulations. Based on the past DEA compliance reviews performed at DCs housing CII controlled drugs, IA has noted the need to formalize the policies and procedures specific to the CII controlled drug process due to recurring issues and unknown procedures to ensure regulatory compliance (see Attachment C for a summary of observations from the previous three CII DC reviews).	If CII controlled drug policies and procedures are not documented and available for reference, employees could make compliance decisions that are not in the best interests of Walgreens. In addition, the continuity of the CII controlled drug process could be negatively impacted in the event of personnel turnover.	<p>The Logistic and Planning Department should develop and update the online compliance manual to include policies and procedures covering the entire CII controlled drug process. The policies and procedures should reflect the current CII controlled drug regulatory environment and cover, at a minimum:</p> <ul style="list-style-type: none"> • Receiving and shipping procedures • DEA Form 222 ordering, processing, and maintenance • CII vault combination changes • Power of Attorney Letter Maintenance • CII return processing <p>In addition, the CII Managers should be contacted to provide input for best practices.</p>	<p>Dan Coughlin, Regional Vice President Distribution Centers and Logistics</p> <p>We are currently compiling the current documentation for review of what is in place at each DC for entry into an on line format. This process will be re-evaluated in May 2009 for the scope of what needs to be entered and time frame.</p> <p>Estimated Completion Date for Scope Evaluation:</p> <p>May 31, 2009</p>

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~~Proposed~~

Attachment B

Code of Federal Regulations

Section 1314 - Retail Sale of Scheduled Listed Chemical Products - Subpart A - General

- Sec. 1314.01 Scope.
- Sec. 1314.02 Applicability.
- Sec. 1314.03 Definitions.
- Sec. 1314.05 Requirements regarding packaging of nonliquid forms.
- Sec. 1314.10 Effect on State laws.
- Sec. 1314.15 Loss reporting.

Sec. 1314.01 Scope.

This part specifies the requirements for retail sales of scheduled listed chemical products to individuals for personal use.

Sec. 1314.02 Applicability.

(a) This part applies to the following regulated persons who sell scheduled listed chemical products for personal use:

1. Regulated sellers of scheduled listed chemical products sold at retail for personal use through face-to-face sales at stores or mobile retail vendors.
2. Regulated persons who engage in a transaction with a non- regulated person and who ship the products to the non-regulated person by the U.S. Postal Service or by private or common carriers.

(b) The requirements in subpart A apply to all regulated persons subject to this part. The requirements in subpart B apply to regulated sellers as defined in Sec. 1300.02 of this chapter. The requirements in subpart C apply to regulated persons who ship the products to the customer by the U.S. Postal Service or by private or common carriers.

Sec. 1314.03 Definitions.

As used in this part, the term "mail-order sale" means a retail sale of scheduled listed chemical products for personal use where a regulated person uses or attempts to use the U.S. Postal Service or any private or commercial carrier to deliver the product to the customer. Mail-order sale includes purchase orders submitted by phone, mail, fax, Internet, or any method other than face-to-face transaction.

Sec. 1314.05 Requirements regarding packaging of nonliquid forms.

~~Proprietary~~**Attachment B**

A regulated seller or mail order distributor may not sell a scheduled listed chemical product in nonliquid form (including gel caps) unless the product is packaged either in blister packs, with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

Sec. 1314.10 Effect on State laws.

Nothing in this part preempts State law on the same subject matter unless there is a positive conflict between this part and a State law so that the two cannot consistently stand together.

Sec. 1314.15 Loss reporting.

- (a) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, any unusual or excessive loss or disappearance of a scheduled listed chemical product under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.
- (b) Each report submitted under paragraph (a) of this section must, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved.
- (c) Written reports of losses must be filed within 15 days after the regulated person becomes aware of the circumstances of the event.
- (d) A report submitted under this section must include a description of the circumstances of the loss (in-transit, theft from premises, *etc.*).
- (e) A suggested format for the report is provided below:

Regulated Person	
Registration number (if applicable)	_____
Name	_____
Business address	_____
City	_____
State	_____
Zip	_____
Business phone	_____
Date of loss	_____
Type of loss	_____
Description of circumstances	

**CII Distribution Center Observation Summary
DEA Compliance Review**

Attachment C

Observations Noted	DC with Cls		
	Perrysburg Q1 - FY09	Jupiter Q4 - FY07	Woodland Q2 - FY07
Closed Stores with DEA Form 222s On-hand: Our review of a sample of closed stores serviced by the DC disclosed the DC had a moderate percentage of closed stores with DEA Forms 222 on-hand.	x	x	x
CII Vault Combination Change Process: DC did not have an effective CII vault combination change process.	x	x	
DEA 222 Form Series Accountability A small percentage of sampled stores disclose the DC had voided DEA Form 222s in the unexecuted file that were not identified in the system as voided.		x	
DEA Form 222 Completeness: Our review of a sample of DEA Form 222s disclosed a small percentage were not completely filled out. The line item was not filled out due to the product not being received.	x		
CII ARCOS Monthly Transaction Report Review: Per the Online Compliance Manual, DCs are required to print off the monthly transaction reports that have been submitted to the DEA to ensure completeness and accuracy of transactions. Discussions with the CII Function Manager disclosed the monthly transaction review is not being performed.	x		

5/4/2009

WAGMDL00757211